REMARKS

Claims 1-2, 6-35, 39-44 and 48 are pending. Claims 7, 17-29 and 41 are cancelled herein. Claims 1, 2, 6, 30 and 39 are amended herein. Support for the amendments to claims 1, 2, 6, 30 and 39 can be found throughout the instant specification as filed. No new matter has been added by way of these amendments. The amendments to the claims should in no way be construed as acquiescence to any of the Examiner's rejections and were made solely to expedite the prosecution of the application. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s).

Objection to the Specification

The Office Action objects to the specification for apparent misspelling of the trade name "ARLATONE®" in reference to recitation of "ARLANTONE MAP 230K40" in Table II at page 17 of the instant specification as filed. Applicants have corrected this misspelling within the replacement copy of Table II submitted herewith. Support for this correction can be found at least at page 15, line 29 of the instant specification as filed. No new matter has been added by way of this correction. In view of this correction, Applicants respectfully request withdrawal of the objection to the specification.

Objection to Claim 6

The Office Action objects to claim 6 for inclusion of an extra period in the phrase "about 0.1 .to 5.0%". Claim 6 is amended herein to remove this extra period. Accordingly, Applicants respectfully request withdrawal of the objection to claim 6.

Statutory Double Patenting Rejection

The Office Action states that claims 1, 6, 9, 12-14, 16-18, 30-35, 39-44 and 48 are provisionally rejected under 35 U.S.C. §101 as claiming the same invention as that of claims 1, 6, 9, 12-14, 16-18, 30-35, 39-44 and 48 of copending Application No. 11/529,096. Applicants respectfully submit that claims 1, 6, 9, 12-14, 16-18, 30-35, 39-44 and 48 of copending Application No. 11/529,096 were cancelled in a prior

Amendment dated September 27, 2006, rendering the instant provisional rejection moot in relation to these claims of Application No. 11/529,096.

Non-Statutory Double Patenting Rejection

The Office Action states that claims 1, 6, 9, 14 and 18 are provisionally rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims 49 and 67-73 of copending Application No. 11/529,096 in view of Murthy *et al.* (WO 01/107010). Applicants submit that because no claims have been deemed allowable in either this application or application 11/529,096, Applicants will postpone action with respect to this rejection unless and until they are notified of otherwise allowable subject matter in either application.

Rejection of Claims 6, 9, 12-14 and 16-18 under 35 U.S.C. §112, First Paragraph

The Office Action rejects claims 6, 9, 12-14 and 16-18 under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. Specifically, the Office Action asserts, "The terms 'zwitterionic organic compound derivatives synthesized from piperazine-N' propane' and 'carboxylic acid derivative of propane' do not fully meet the written description provision . . . due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities." Solely in the interest of expediting prosecution of the instant application, claim 6 is herein amended to require that "said anti-inflammatory agent is selected from the group consisting of a long chain aliphatic ester of [HEPES], an ether analog of HEPES and a urethane derivative of HEPES" and that "said pH-control agent and antioxidant agent is citric acid". Applicants respectfully submit that one of ordinary skill in the art would recognize Applicants' possession of these recited compounds at the time of filing, as such compounds are precisely identified within the instant specification as filed.

The Office Action also rejects claim 17 under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement because "[t]he presence of sodium borage-amidopropyl hydroxyphosphate, identified as a surfactant, is required in [claim 17; and] 'Borage' is not a standard word used in naming chemical

compounds and the compound described in this claim cannot be determined." Solely in the interest of expediting prosecution of the instant application, claim 17 has been cancelled herein, rendering the instant rejection of claim 17 moot.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 6, 9, 12-14 and 16-18 under 35 U.S.C. §112, first paragraph.

Rejection of Claims 2, 6 and 9 under 35 U.S.C. §112, Second Paragraph

The Office Action rejects claims 2, 6 and 9 under 35 U.S.C. §112, second paragraph, for alleged indefiniteness. Specifically, claim 2 is rejected for recitation of the term "generated in an environment that is substantially free from a sponge". Solely in the interest of expediting prosecution of the instant application, Applicants have herein amended claim 2 to require that "the foam is generated in a device that does not contain a sponge". Support for this amendment to claim 2 can be found at least at page 11, lines 11-13 of the instant specification as filed. Applicants respectfully submit that claim 2 as amended is clear and definite.

Claim 6 is rejected for recitation of:

> [T]he items "potassium lauryl phosphate polysorbate 60" and "potassium tridecyl phosphate polysorbate 60" . . . From the structure of polysorbate 60 and either potassium lauryl phosphate or potassium tridecyl phosphate (each of which also appear in the list), the Examiner was unable to determine the structure of these names as one chemical compound and wonders if Applicant means these two compounds in combination with each other . . . In the Markush group for item (g) is "phenoxyethanol and diazolidinyl urea propylene glycol/methyl-propyl paraben". The "and" indicates what follows is the final item in the Markush group. It could not be determined if the various compounds, as separate compounds, were all present in the composition, or if all of molecules are joined in some fashion to produce one molecule. In using the specification to try and interpret the claims, it was noted that formulation A and B contain diazolidinyl urea, methylparaben and propylparaben but no propylene glycol, which based on the format present, refers to the three separate components being present in the compositon

Solely in the interest of expediting prosecution of the instant application, claim 6 is herein amended to require "a first water soluble surfactant present in the range of about 0.02-20% by weight, said first surfactant selected from the group

consisting of sodium lauryl sulfate, potassium lauryl phosphate, polysorbate 60, and potassium tridecyl phosphate" and "a microbiological preservative present in the range of about 0.01-5.7% by weight and selected from the group consisting of phenoxyethanol urea, diazolidinuyl urea, propylene glycol, methyl parabens, ethyl parabens and propyl parabens". Applicants respectfully submit that claim 6 as amended is clear and definite.

Claim 9 is rejected for recitation of "the limitation 'an ester of HEPES'. There is insufficient antecedent basis for the abbreviation HEPES in the claim." Solely in the interest of expediting prosecution of the instant application, claim 9 is amended herein to depend from claim 8, providing sufficient antecedent basis for recitation of the abbreviation "HEPES" in claim 9. Accordingly, Applicants respectfully submit that claim 9 as amended is clear and definite.

In view of the above, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 2, 6 and 9 under 35 U.S.C. §112, second paragraph.

Rejection of Claims 1, 2, 30-35, 39-44 and 48 Under 35 U.S.C. §102(b)

The Office Action rejects claims 1, 2, 30-34, 39-43 and 48 under 35 U.S.C. §102(b) as allegedly being anticipated by Viola (US 3,962,150). Applicants respectfully traverse this rejection. For a prior art reference to anticipate a claimed invention, the prior art must teach ***each and every element*** of the claimed invention. *Lewmar Marine v. Barient*, 827 F.2d 744, 3 USPQ2d 1766 (Fed. Cir. 1987).

Viola does not teach each and every element of the claimed invention. Viola fails to describe a "cleanser composition . . . in the form of a controlled concentration foam suitable for direct application to an eyelid of a subject, ***wherein said cleanser composition comprises an anti-inflammatory agent***" (***emphasis added***). Viola discloses a

> [F]oam-producing skin cleansing composition which comprises a total surfactant composition of from 1 to 15% having from 0.5 to 14.5% by weight of a nonionic surfactant and from 0.5 to 14.5% by weight of an anionic surfactant; from 1.0 to 15.0% of an alcoholic solvent selected from the group consisting of monohydric alcohols having from 2 to 3 carbon

> atoms, glycol ethers, polyhydric glycols and mixtures thereof; and from 70 to 98% by weight of water[.] (Viola '150 patent, column 2, lines 21-30)

Viola fails to disclose or suggest a controlled concentration or transiently stable cleanser foam suitable for direct application to an eyelid of a subject ***that comprises an anti-inflammatory agent***, as amended claims 1, 2, 30-34, 39-43 and 48 require. Thus, Viola fails to anticipate the claimed invention, as it fails to disclose or suggest each and every element of the instant claims.

The Office Action also rejects claims 1, 2, 30-32, 35, 39-41, 44 and 48 under 35 U.S.C. §102(b) as allegedly being anticipated by Faryniarz *et al.* (US 5,429,815). Applicants traverse this rejection, as Faryniarz *et al.* does not teach ***each and every element*** of the presently claimed invention. Faryniarz *et al.* discloses "a concentrate-propellant system for a self-foaming cleanser that achieves increased miscellization and solubilization of propellant within the aqueous fluid of the system." Faryniarz *et al.* fails to disclose or suggest a "cleanser composition . . . in the form of a controlled concentration foam suitable for direct application to an eyelid of a subject, ***wherein said cleanser composition comprises an anti-inflammatory agent***" (***emphasis added***), as amended claims 1 and 2 require. Nor does Faryniarz *et al.* disclose or suggest a "transiently stable foam . . . suitable for direct application to an eyelid of a subject . . . ***wherein said [cleaning agent or cleanser composition] comprises an anti-inflammatory agent***," as amended claims 30-32, 35, 39-41, 44 and 48 require.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 2, 30-34, 39-43 and 48 under 35 U.S.C. § 102(b).

Rejection of Claims 1, 6, 9, 12-14 and 16-18 Under 35 U.S.C. §103(a)

The Office Action rejects claims 1, 6, 9, 12-14 and 16-18 under 35 U.S.C. § 103(a) as allegedly unpatentable over Niemiec *et al.* (EP 1060732) in view of Pugliese *et al.* (US 6,114,337), Malik *et al.* (WO 01/23517) and Simion *et al.* (US 5,480,633). Applicants respectfully traverse this rejection. To establish a *prima facie* case of obviousness, the Examiner must establish that the prior art included each element claimed (M.P.E.P. 2143). In addition, "[a] patent composed of several elements is not

proved obvious merely by demonstrating that each element was, independently, known in the prior art." *KSR International Co. v. Teleflex Inc.* 167 L. Ed. 2d 705, 712.

The combination of Niemiec *et al.*, Pugliese *et al.*, Malik *et al.* and Simion *et al.* fails to obviate the claimed invention. Niemiec *et al.* discloses "a vesicle delivery system for topically delivering benefit agents into and/or onto the skin and hair, in the optional presence of detergents" (Niemiec *et al.*, page 6, lines 22-23). Niemiec *et al.* fails to describe or suggest a "cleanser composition . . . in the form of a controlled concentration foam ***suitable for direct application to an eyelid of a subject***, wherein said cleanser composition comprises an anti-inflammatory agent" (***emphasis added***), as instant claims 1, 6, 9, 12-14 and 16-18 as amended require. Addressing the nature of a cleanser composition that is "suitable for direct application to an eyelid of a subject," the instant specification states,

> To support the skin's functions, it is therefore important to use skin care products with a physiological pH ideally close to the skin's pH of 5.5. In addition, it is important to stabilize the skin's natural protective acid mantle to optimize its ability to withstand infection. ***Accordingly the pH range of the composition is best kept about 5.5-6.5, inclusive.*** Citric acid is a preferred pH control agent. (***emphasis added***)

Indeed, maintenance of a pH that is not overly acidic is critical for a cleanser composition that is applied to the eyelid of a subject, in view of the danger of an overly acidic composition causing burning or stinging of the eye of a subject. Specifically, solutions of less than pH 4 are recognized in the art to cause acidic eye injuries (Ocular Therapeutics Handbook: A Clinical Manual (2nd Edition; 2005) Onofrey, Bruce E; Skorin, Jr., Leonid; and Holdeman, Nicky R., page 339, attached herewith as Appendix A). Thus, the limitation "suitable for direct application to an eyelid of the subject" in claim 1 is not simply a recitation of intended use. Because Niemiec *et al.* discloses vesicle delivery system formulations having pH values as low as 4.0 ± 0.2, and lacks any teaching or suggestion addressing how such compositions could be rendered "suitable for direct application to an eyelid of the subject," as the instant claims as amended require, Niemiec *et al.* fails to disclose or suggest all elements of the instant claims.

Pugliese *et al.*, Malik *et al.* and Simion *et al.* do not make up for the deficiencies of the primary reference of Niemiec *et al.* Specifically, Pugliese *et al.* discloses

> [A] composition and method for the treatment of inflammatory conditions in mammals, by the topical administration of selected Zwitterionic ester compositions, serving as safe and effective substances. Among useful Zwitterionic compounds which are presently preferred; these include EPES, PIPES, BES, POPSO, and most preferably HEPES, when esterified, then alone, or in combination with other therapeutic ingredients. They are employed by applying to an affected area of the skin, a therapeutically effective amount of at least one skin compatible, Zwitterionic-Ester . . . (Pugliese *et al*. '337 patent, column 2, lines 39-50).

Pugliese *et al*. fails to disclose or suggest a composition that is "***a controlled concentration foam***" and also fails to address how the skilled artisan might adapt the disclosed anti-inflammatory compounds to render them "suitable for direct application to an eyelid of the subject," as the instant claims require.

Malik *et al.* describes a "combination of surfactants . . . that are very mild (gentle) to the skin and eye tissues such that they cause minimal, if any, irritation of these tissues." Exemplary compositions of Malik *et al*. have stated pH values in the range of 7.1-7.8, and Malik *et al*. further states that "[the compositions] do not require the presence of ancillary materials to achieve levels of foam generally desired by consumers." However, Malik *et al.* fails to disclose or suggest a "cleanser composition . . . in the form of a controlled concentration foam suitable for direct application to an eyelid of a subject, ***wherein said cleanser composition comprises an anti-inflammatory agent***" (***emphasis added***), as the instant claims require.

Simion *et al*. discloses:

> [A]n aqueous skin rinse formulation for soap and surfactant residue removal consisting of a minimal amount of a water soluble nonionic surfactant such as the polyethylene oxide--condensates of higher fatty alcohols, and a polysorbate containing 20 moles of ethylene oxide, a minimal amount of an organic acid having a pKa of 4.5 to 6.5 and/or a monovalent cation salt of the acid, and a major amount of water in an amount of about 84-98% by weight of the liquid formulation having a pH within the range of about 4.5-6.5. (Simion *et al*., '633 patent, column 1, lines 11-20)

Simion *et al*. fails to describe or suggest a "cleanser composition . . . ***in the form of a controlled concentration foam*** suitable for direct application to an eyelid of a subject, ***wherein said cleanser composition comprises an anti-inflammatory agent***" (***emphasis added***), as the instant claims require.

Niemiec *et al.*, Pugliese *et al.*, Malik *et al.* and Simion *et al.* together fail to describe or suggest a "cleanser composition . . . in the form of a controlled concentration foam suitable for direct application to an eyelid of a subject, wherein said cleanser composition comprises an anti-inflammatory agent," as the instant claims require. Applicants submit that the presently claimed invention is not a simple substitution, predictable extension or anticipated result of the prior art at the time of filing and that, at least in view of the above, the skilled artisan would not have found it obvious to assemble various independent components that are arguably found in the prior art into the specific composition that is presently claimed.

Because the combination of Niemiec *et al.*, Pugliese *et al.*, Malik *et al.* and Simion *et al.* does not arrive at the claimed invention, a *prima facie* case of obviousness over the claims has not been established. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 6, 9, 12-14 and 16-18 under 35 U.S.C. §103(a).

SUMMARY

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Dated: January 21, 2009

Respectfully submitted,

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